Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
Sent: 5/10/2018 7:50:46 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Pruitt Resumes Courting Industry as Ethics Controversies Swirl

By Jennifer A. Dlouhy and Ari Natter

Posted May 9, 2018, 6:34 PM

Embattled EPA Administrator Scott Pruitt is seeking to shift the limelight away from questions about his ethics and instead focus attention on his efforts to eliminate regulations on oil drillers, farmers, home builders, and automakers.

Industry Clamors for EPA's Ear on Revising Cost-Benefit Reviews

By Abby Smith

Posted May 9, 2018, 3:08 PM

Industry groups are lining up to share their thoughts on how the EPA should evaluate the costs and benefits of regulations differently, just as the agency is poised to release an overhaul of its approach.

Asbestos Controls, Testing Flame Retardants Among New EPA Rules (1)

By Pat Rizzuto

Posted May 9, 2018, 1:23 PMUpdated May 9, 2018, 6:00 PM

The EPA would restrict some uses of asbestos and require manufacturers to generate new toxicity data for some flame-retardant chemicals under updated regulatory plans the agency released May 9.

EPA Obscures Deadline for Science Transparency Plan

By Sylvia Carignan

Posted May 9, 2018, 1:07 PM

The EPA has yet to release a timeline for its plans to increase the transparency of the scientific studies it uses to set environmental protection standards, according to the Office of Management and Budget's regulatory agenda released May 9.

INSIDEEPA.COM ARTICLES

House Vote Bolsters Critics' Efforts To Kill EPA Policies Under 'Review' Act

Congress has approved a first-time Congressional Review Act (CRA) resolution repealing a years-old agency guidance, a measure that appears likely to bolster efforts by deregulatory opponents, who are currently seeking a precedent-setting court ruling that would allow them to enforce the law's mandate that agencies submit such documents to Congress for approval or disapproval.

GREENWIRE ARTICLES

Half-hour of confusion at Pruitt's condo

Kevin Bogardus and Hannah Northey, E&E News reporters

Published: Thursday, May 10, 2018

EPA Administrator Scott Pruitt rented this Capitol Hill condominium from the wife of a lobbyist whose clients lobbied EPA. Kevin Bogardus/E&E News

One March evening last year, the Washington, D.C., fire department dispatched an emergency team at 5:18 p.m. — someone was reportedly unconscious.

First responders from Engine Co. 3 raced to the other side of Capitol Hill, arriving just five minutes later at a plush condo building down the street from Senate office buildings. The sequence of events as recorded by the dispatch center indicates concern over what prompted the call, according to the incident report obtained by E&E News under a public records request.

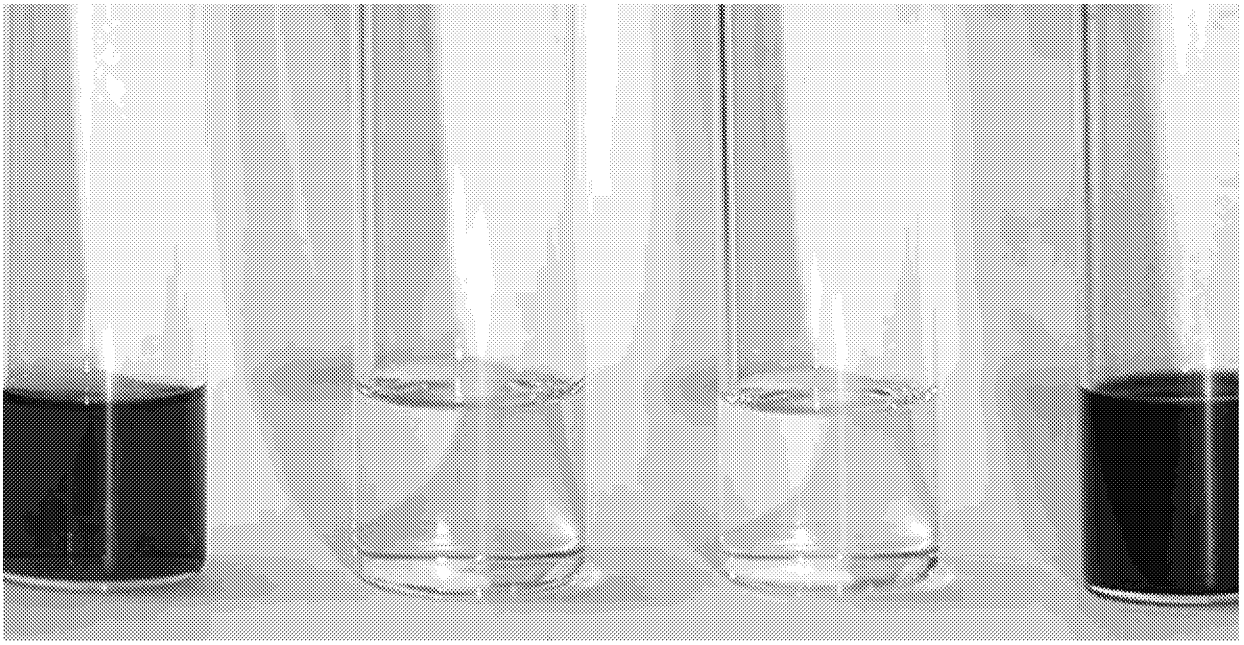
With some redacted words legible under light, the report's narrative reads, "The caller is unable to assess the patient's breathing status" and "He is still unconscious." Other notes hint at the confusion on the scene, such as "Fainting" and "Conscious, Breathing."

https://www.eenews.net/greenwire/2018/05/10/stories/1060081395

Surprise: EPA will finalize Obama curbs on paint stripper

Corbin Hiar, E&E News reporter

Published: Thursday, May 10, 2018



EPA has pledged to take action on methylene chloride. LHcheM/Wikimedia Commons

In an unexpected move, EPA said today it "intends to finalize" an Obama-era proposal that sought to restrict the sale of a deadly paint-stripping chemical.

The agency also announced it wouldn't re-evaluate "the paint stripping uses of methylene chloride and is relying on previous risk assessments," which found the chemical can trigger asphyxiation and heart attacks. The 2011 risk assessment also determined that long-term exposure can cause cancer and damage to the liver and kidneys.

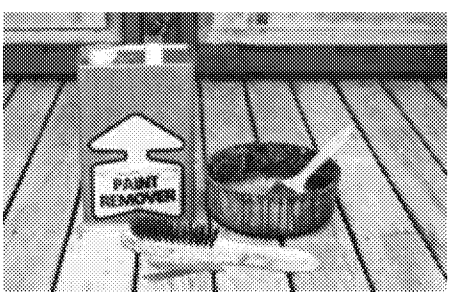
https://www.eenews.net/greenwire/2018/05/10/stories/1060081379

CHEMICAL WATCH ARTICLES

Methylene chloride campaigners meet with EPA Administrator

Pressure mounts on Pruitt

9 May 2018 / Built environment, Solvents, United States



NGO campaigners have met with EPA Administrator Scott Pruitt to request that the agency act on its proposed rule to ban methylene chloride paint strippers.

The meeting is the latest development in a months-long push for action on the paint removal products, which have caused dozens of consumer and worker deaths in recent years.

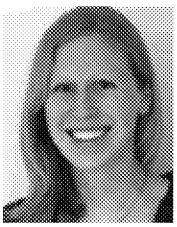
Mr Pruitt has continued to insist that the proposal – which was issued in the final days of the previous administration – has not been dropped, but rather is under review.

But NGOs and families of those who have died using the products are urging the agency act immediately.

Cindy Wynne – the mother of a South Carolina man who was killed while using a paint stripper containing methylene chloride – added that while she appreciated the meeting, Mr Pruitt's "words of consolation and explanation" are insufficient.

Meanwhile, NGO Safer Chemicals, Healthy Families is leading health advocacy groups in a "week of action" in dozens of states demanding that Lowe's home improvement stores pull the products from their shelves.

Under the organisation's Mind the Store campaign, more than 120,000 consumers have petitioned the company to stop selling the paint strippers.



Kelly Franklin

North America editor

Related Articles

- US EPA proposes prohibitions on methylene chloride, NMP
- Pruitt: EPA may act on methylene chloride ban 'this year'
- Restrictions on methylene chloride, NMP, TCE apparently shelved by US EPA
- NGOs push Lowe's on methylene chloride paint strippers

Further Information:

- Statement on Pruitt meeting
- 'Week of action'

Anses warns against hazardous substances in homemade toy 'slime

9 May 2018 / Children's products, France, Substances of concern

Homemade toy 'slime' can pose health risks to children as they may contain hazardous substances, the French Agency for Food, Environmental and Occupational Health and Safety has warned.

Several cases of skin damage related to the product have been reported to the agency, poison control centres and various allergy control networks, Anses said.

The slime kits have become very popular with younger children and teenagers in France, and tutorials on the internet on home fabrication have increased interest in the product.

In a joint warning with the French Directorate-General for Competition, Consumer Affairs and Fraud Control (DGCCRF), Anses said detergents and adhesives used in homemade slime contain allergenic or irritant preservatives that are not meant to be handled in large quantities, repeatedly and for a prolonged time.

Liquid adhesives – the most common ingredient – contain preservatives such as formaldehyde liberators or isothiazolinones, which are "very allergenic substances", as well as many solvents, which can cause irritation of the airways and damage to the central nervous system, Anses said.

The majority of online do-it-yourself recipes also contain boron compounds. These substances, intended for cleaning contact lenses or as detergents, are reprotoxic, may impact foetal development and "must not be manipulated by children repeatedly", it said.

The DGCCRF also conducted a survey of slime kits sold in shops. Of the 15 samples analysed, two contained a boron content exceeding the permissible limit and were withdrawn from the market. The DGCCRF will continue its market controls in 2018.

Last month, the Norwegian Environmental Directorate removed some ready-made slime products from the market, after it found they contained high levels of lead and arsenic.

Related Articles

- Norway bans 'slime' toy products containing lead, arsenic

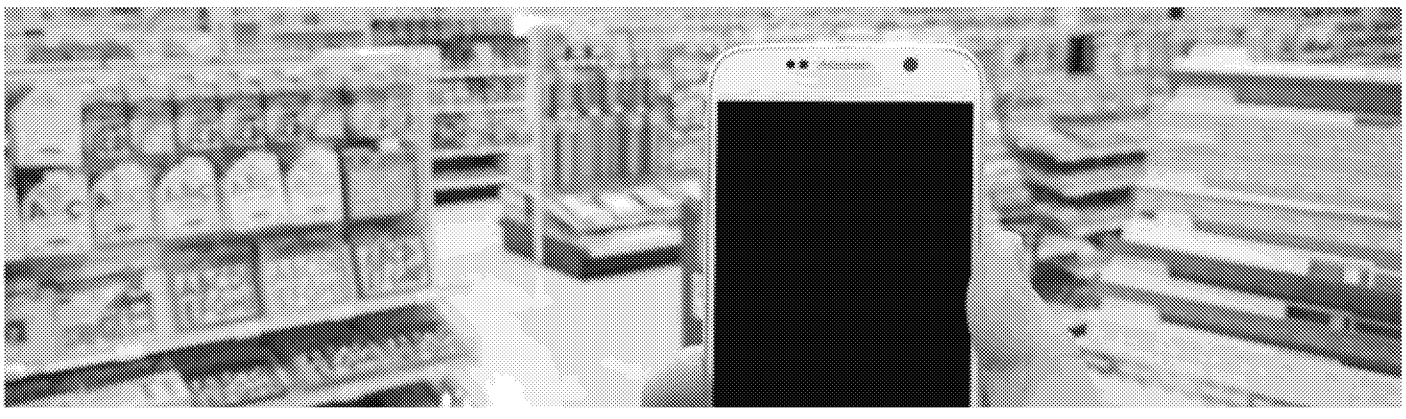
Further Information:

- Anses press release (in French)

There's an app for that

The AskREACH project aims to make Article 33 of REACH work better by enabling consumers to track SVHCs in articles

Global Business Briefing, May 2018



The duty of suppliers of articles containing substances of very high concern (SVHCs) at concentrations above 0.1% w/w in an article, including – as per a European Court of Justice (ECJ) ruling in 2015 – each article "incorporated as a component of a complex product", is enshrined in REACH Article 33. What is happening in practice is quite another matter.

Article 33 stipulates that suppliers "shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance". It also requires suppliers to provide consumers with the same information, free of charge, within 45 days of receiving a request.

Recently, representatives of industries including automotive, electronic, aerospace, apparel, furniture and chemicals began discussions on collecting and sharing material data for articles, including their chemical composition. Although they have their own material declaration systems, there is little information sharing and it is recognised that a common approach could:

- facilitate the collection and sharing of material
- composition information;
- allow companies to better identify SVHCs; and
- ensure compliance as regulations change.

This would be particularly helpful to upstream companies, which currently receive multiple requests for the same or similar information in multiple formats. An accord is some way off as there has to be agreement on such thorny issues as a common data structure, the level of detail to be communicated, data quality and data security.

When implementing legislation, says Martin Führ, professor of public law, comparative theory and legal theory at Hochschule Darmstadt University of Applied Sciences in Germany, it is important to follow the legislators' intentions as well as the letter of the law. In this case, it is clear that REACH aims to substitute SVHCs with other solutions.

Moreover, he says, Article 1, which aims for a high level of protection for health and environment, requires "a dynamic approach, involving the actors in the supply chain directly. No interference by public authorities as such is needed." Obviously the definitions in Article 33 are extremely broad.

A 'supplier' could be a producer, distributor or other actor in the supply chain. An 'article' can be tiny but, as the principle states, "once an article, always an article", as the ECJ also established in 2015. 'Placing on the market' can mean simply selling it, but also holding it as stock in an online shop or offering it free of charge, such as a paper towel in a public restroom. All in all, says Professor Führ, "it's difficult not to be a supplier of an article".

These findings are mirrored when it comes to the question who is entitled to a consumer request: REACH does not define a 'consumer'; but from a legal perspective, a consumer does not necessarily have to be a buyer. Downstream users are excluded, as they are covered by Article 32 (1), but all other natural and legal persons are entitled to ask for information - possibly including the authorities in their role as buyers of articles.

"Behind Article 33 is the duty to cooperate with other actors in the supply chain," Professor Führ says. "This is not written in the legal text but it is the precondition that the whole system works on."

For consumers to be informed, as the legislators clearly intended, there has to be transparency and traceability. This has the extra benefits of complying with product safety and liability requirements.

There are many ways to comply with Article 33. Often, they can be rather unhelpful. For example, some major electronic goods suppliers have put generic information on the internet about how some of their hundreds of products "might contain" unspecified SVHCs, saying that they all do to be on the safe side, or sending test results running to many pages, which may not refer to SVHCs or may be out of date because the candidate list has since been updated.

This will no longer be acceptable, Professor Führ says. The EU's circular economy package is on its way and a provision in that links Article 33 to a central database that Echa will host. This is due to go online in 18 months, with obligations starting after 30 months' time.

The upcoming review of the waste framework Directive is another relevant issue here. In March, a proposed amendment was added to Article 9, requiring suppliers to notify Echa of the presence of SVHCs in articles. This followed on from a European Parliament vote to adopt other proposed changes with the specific aim of ensuring a 'progressive substitution' of SVHCs.

The issue also goes beyond the EU framework. It addresses initiatives like the Strategic Approach to International Chemicals Management (Saicm) and the UN's Sustainable Development Goals (SDGs), particularly SDG 12, 'Ensure sustainable consumption and production patterns', for which targets are due in 2020. "Article 33 could have been really helpful to reaching this SDG," says Professor Führ.

Ten years on from REACH coming into force, however, implementation of Article 33 has barely begun. A report by Echa in 2016 showed very low consumer awareness of the right to request information and various studies of compliance have shown that it is not functioning properly.

For instance, in a study commissioned in Belgium by DG Environment in 2016, only 23% of the companies selling construction materials which were sent a request about the presence of SVHCs in their products replied within 45 days.

Of those which did:

- some provided a formal letter of declaration, of the kind they send to downstream users, stating that no SVHCs were present
- in their products;
- some did not understand the request or declined to provide information; and
- some said that they were not obliged to provide information because the request had not been made by a consumer.

"There are various reasons why the system does not work well," says Arno Biwer, senior R&T associate at the Luxembourg Institute of Science and Technology. "Limited awareness among consumers, retailers and suppliers about their rights and obligation; difficulties for consumers in making requests; suppliers' answers being inadequate or wrong, or just not answering. All of this leads to risks to human health and the environment."

In any case, adds Professor Führ, today's consumers see no point in asking questions in a shop that may or may not be answered 45 days later. They want answers immediately. The only viable way to address that is to use mobile apps to scan information from barcodes on the products themselves.

Denmark has already pioneered this approach and the lessons learned there are informing ongoing initiatives. The Tjek Kemien app was launched in 2014 and trialled with the country's two largest supermarkets. In 2016, there were 88 requests but in the first two months of 2018, 100m consumer visits to the Co-op generated only three requests,

according to Jakob Lamm Zeuthen, head of environment policy at the Danish Chamber of Commerce, which represents retailers.

This failure had multiple causes, he says. Consumers are mostly concerned about food and cosmetics, but these were not in the scope of the project. "The scan went to the wrong person in the company, or was lost, or the information was difficult to understand, or people lost interest after waiting for 45 days. Retailers don't want to upload SVHC details into database: they want to answer consumers directly by email, so as to maintain trust with them."

In late 2016, Mr Zeuthen adds, the Danish Consumer Council tested the information on the barcodes of 58 hardware products for the presence of phthalates from the SVHC list. Of these, 8 (31%) incorrectly stated that there were no SVHCs when there were. Usually, this was because the barcodes did not work. No answer was received in many cases and some replies were very late. Key causes of misinformation included:

- difficulty in obtaining suppliers' declarations;
- lack of understanding of how to check these declarations;
- wrong or inadequate information from producers;
- lack of understanding about what questions to ask producers;
- different results from tests on the same product by different bodies; and
- an unclear definition of articles as opposed to products.

The pressure for information is still growing, thanks in part to a press article in January 2017 about consumers buying products containing hormone-disrupting chemicals, and partly as a result of these tests. Both the press and the authorities in Denmark have been urging retailers to act.

The Danish EPA, the Chamber of Commerce, industry and building centres consequently formed a partnership that ran from September 2017 to January 2018. The aim was to solve the reasons for misinformation and help retailers in all sectors fulfil their Article 33 obligations.

Working with consultants, the partners have now created guidelines to ensure that information about candidate list articles is collected and passed through the supply chain consistently in the same format until it reaches consumers.

They have also created a tool to train purchasers in where to look for SVHCs in articles and identify those with highest risk of containing them.

Based on this experience, Mr Zeuthen concludes that what works best for companies is also likely to work better for consumers. Retailers, he agrees, would like to have an EU-wide app that takes their needs into account. He also recommends:

- creating a helpdesk to make it easier for retailers to upload information that is useful for consumers and give reminders of when to update;
- sufficient ongoing verification of data, so as to build trust and exclude misleading information. This is not a business obligation;
- keeping food and cosmetics completely outside the database and making it clear this is only about articles; and

- giving the app a name that does not overpromise - in hindsight, 'Tjek SVHCs' would have been better than 'Tjek Kemien'.

On a pan-European scale, the AskREACH project started in September 2017 and will run for five years. It is coordinated by the German Environment Agency, with 19 partners from 13 member states, including NGOs, authorities and research institutes. AskREACH will mainly produce:

- an EU-wide app for consumers, which will be adapted to each member state, in terms of language but also specific information about any aspects particularly relevant in any of them; and
- a central European database, where article suppliers and retailers can upload information of their articles via a barcode, including SVHC details and where within the article any SVHC(s) are contained.

Two apps already exist in Germany, ToxFox and Scan4Chem, and companies involved in those are part of the consortium, as well as the creators of Tjek Kemien, Mr Biwer says. Thus, AskREACH will be able to apply lessons from these projects, learning from the deficiencies of a national approach.

"The principle is similar. You scan the barcode and receive information directly from the database if available; if it is not, a request can be sent automatically to the barcode owner and the retailer to get an individual answer, and the barcode owner can update the database," he explains.

AskREACH will make the database as easy as possible to use, including:

- bulk uploading of articles;
- automatic updating of information on SVHCs if any changes are made in article composition;
- a standardised data exchange format so that information in existing internal company tools can easily be transferred; and
- compatibility with the Echa database, so that requests can be made in standardised way.

Supplier and retailer duties to the app users will be fulfilled by uploading information, because everything else will be done automatically. Different language versions will use standard sentences so that most translation is done directly.

Professor Führ, who is also involved in the project, hopes to see an additional option of declaring that there are no SVHCs in a product, in order to increase transparency and traceability. Suppliers who feed the database can benefit from the option to offer additional, more detailed information on the scanned article, such as via a link to a company website.

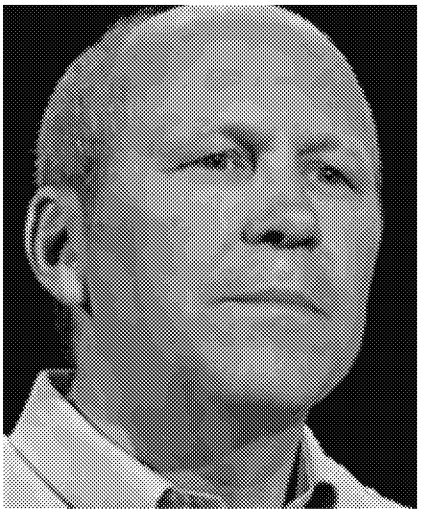
Currently, the project partners are benchmarking the challenges companies are facing, the tools they are using and how to adapt these if needed. Professor Führ says that there are already tools to hand that are "comprehensive, effective, reliable and flexible", as well as and capable of addressing confidential business information (CBI) issues.

The app is due to be launched in April 2019 and AskREACH is inviting companies to participate and to test the tools and give input on possible improvements. "This will give you an opportunity to have an impact early on and show your willingness to take care of consumers' concerns," says Mr Biwer.

Of course, there are technical challenges to overcome, as Professor Führ recognises. "One will be how to identify an article. The supply chain sometimes uses the same barcode for different products and different versions or batches of them. This needs to be addressed when the article identifier system is enhanced," he says.

His concluding advice is: "To all those who are covered by the definition of supplier, be prepared to address a lot of issues." There are a lot of customer demands for information and they might be driven by consumer requests once the European app is available and workable, he says.

"Be prepared for increasing awareness from investors and be aware that existing products as well as new ones are covered. At least consider how to address this, as well as updates of the candidate list and similar lists in other parts of the world."



Dr Andrew Warmington

Commissioning editor, Chemical Watch

Related Articles

- European Court of Justice rules on SVHCs in articles

US body seeks nominees for flame retardant hazard assessment

National Academies plan to inform CPSC OFR rulemaking

10 May 2018 / Built environment, Children's products, Electrical & electronics, Halocarbons, United States

A National Academies committee is recruiting people to help assess organohalogen flame retardants, following a request from the US Consumer Product Safety Commission (CSPC).

The National Academies of Sciences, Engineering, and Medicine's (NASEM) board on environmental studies and toxicology is forming a committee to develop a scoping plan to assess additive, non-polymeric organohalogen flame retardants (OFRs) for their potential chronic health hazards.

Their findings will ultimately be used to inform a CPSC assessment of the risk these substances pose to human health from the following four consumer products categories:

- children's products;
- upholstered residential furniture;
- mattresses; and

- the external casings of electronics devices.

The CPSC's request follows its September decision to grant an NGO petition to begin a rulemaking process under the Federal Hazardous Substances Act (FHSA). It could see OFRs banned from these applications.

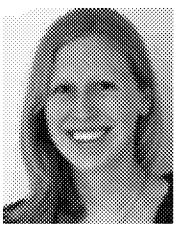
To start this, the CPSC will convene a Chronic Advisory Panel (CHAP) – a group of experts charged with evaluating the scientific evidence on the substances. NASEM will provide the hazard assessment plan which the CHAP will use – together with exposure data – to complete a quantitative risk assessment.

To develop its scoping plan, the NACEM committee will:

- review existing hazard data and identify gaps;
- evaluate the potential for treating OFRs as a single class of substances, for purposes of a hazard assessment; and
- determine recommendations for how to conduct additional research to evaluate OFRs under the FHSA.

NASEM is seeking individuals with expertise in toxicology; epidemiology; pharmacology; statistics and modeling; QSAR/SAR; and risk assessment.

Nominations will be accepted through 20 May.



Kelly Franklin

North America editor

Related Articles

- US CPSC investigates possible action against organohalogen flame retardants

Further Information:

- Call for nominees

Belgian nano registrations 'need improvement'

10 May 2018 / Belgium, Nanomaterials, Substance registration

The quality of registrations for nanomaterials submitted to the Belgian national register needs to be improved, the country's Federal Public Service for Public Health (FPS) said.

In its first report about the nanoregister since its launch in 2015, FPS said an evaluation of submitted registrations showed quality can be improved. It added that not all potential registrants are aware of the obligation to register under a 2014 Royal Decree.

About 77% of the registrations were updated before the April 2017 deadline, the report said.

Importers submitted 56% of the registrations, while distributors and manufacturers accounted for 22% and 11% respectively.

Around a third of the 'active' accounts – those created for one or more registrations – were registered on a voluntary basis, with the remaining two thirds coming from those placing the nano substances on the market themselves, the report said.

Half of the 475 nanomaterials registrations made in 2016 concerned substances in quantities below one tonne, and would therefore be considered out of scope of REACH.

Amendments

EU member states have recently agreed on changes to REACH annexes to address specific requirements for nanomaterials.

The amendments, due to come into effect in 2020, include a provision giving Echa the legal right to request additional information on substances above ten tonnes when safety of those substances is not demonstrated.

NGOs had pressed for the provision to apply to all REACH registered nanomaterials above 1 tonne.

Substances registered to Belgian authority in quantities of more than 1,000 tonnes were:

- amorphous silica;
- calcium carbonate;
- calcium carbonate treated with stearic acid;
- carbon black;
- diiron trioxide;
- iron hydroxide yellow; and
- silicon oxide.

European action

In June last year, Echa launched its EU observatory for nanomaterials (EUON), a public website aimed at increasing transparency of information on nanomaterials on the EU market.

This comes after the Commission opted not to create an EU nano register, given delays in the introduction of new REACH information requirements for nanomaterials.

Elsewhere in Europe, Denmark, France, Norway and Sweden also require companies to report information on nanomaterials to their national inventories.

Related Articles

- Member states agree nanomaterial changes to REACH annexes
- Echa launches EU nanomaterials observatory

- Nano data will be added to Swedish product register next year

Further Information:

- Executive summary

Canada clears EDTA and salts, no further action needed

10 May 2018 / Canada, Environmental Protection Act, Risk assessment

The Canadian government has finalised its assessment that ethylene diaminetetraacetic acid (EDTA) is not harmful and requires no action under the Canadian Environmental Protection Act, 1999 (Cepa). The decision also clears three EDTA salts:

- tetrasodium;
- ferric monosodium; and
- ferric ammonium.

The assessment, published on 5 May, finalises the conclusions of a draft assessment from May 2017.

EDTA and tetrasodium EDTA are used as chelating agents and preservatives in a wide range of products.

The government's assessment concluded – "on the basis of the available empirical data" – that none of the substances were carcinogenic or genotoxic.

Studies showing other adverse effects from oral exposure were "compromised" by "excessively high" doses, and the substances are "of low toxicity" at lower doses, the assessment found.

Related Articles

- Canada provisionally clears EDTA and salts

Further Information:

- Canada Gazette

US NTP requests data on identifying developmental toxicants

Information will inform effort to develop animal testing alternatives

10 May 2018 / Alternative approaches to testing, Test methods, TSCA, United States

The US National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods is requesting data on approaches for identifying potential developmental toxicants.

Niceatm provides scientific and operational support to the Interagency Coordinating Committee on the Validation of Alternative Methods (Iccvam), which is charged with implementing a strategy for new, non-animal approaches to evaluating the safety of chemicals and medical products.

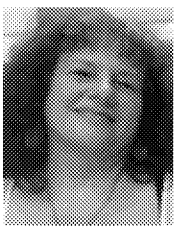
The project is required under the 2016 amendments to TSCA, which set a goal to reduce and eventually replace vertebrate animal testing under the programme.

In March, the EPA published its draft strategy for promoting the development and implementation of alternative test methods. And the agency recently issued guidelines on alternative test methods for determining skin sensitisation.

The new data request, published in the 5 May *Federal Register*, will feed into the ongoing initiative. The information "will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce adverse effects in offspring".

Niceatm specifically requested information "relevant to the development or validation of alternatives to *in vivo* developmental toxicity test methods currently used by federal agencies for regulatory and other decision contexts". It also asked for data from animal or human studies evaluating the same chemicals for comparison.

The deadline for submissions is 15 June.



Julie Miller

Reporter

Related Articles

- Iccvam makes 'significant progress' on implementation plans for NAMs
- US EPA publishes draft strategy to promote alternative tests
- US EPA drafts approach to non-animal testing for skin sensitisation

Further Information:

- Federal Register notice

Australian panel says PFAS ill-health links limited or non-existent

Concerns remain unanswered says MP from affected area

10 May 2018 / Australia, PFCs, Risk assessment

A report from Australia's Expert Health Panel for PFAS has concluded that evidence linking exposure to polyfluorinated substances (PFASs) with human disease is limited or non-existent, and that there is "no current evidence that suggests an increase in overall cancer risk".

The panel, established in October last year to advise the government, reviewed 20 Australian and international reports and reviews examining potential health effects of exposure to PFASs, as well as carrying out a public consultation.

The conclusions concur with advice from the country's health department that "there is no current evidence that supports a substantial impact on an individual's health from PFAS exposure."

PFASs are bioaccumulative substances that were present in fire-repellent foams widely used in Australian military airbases across the country from the early 1970s. The decision to phase them out was made about ten years ago.

They have been linked with long-term health problems.

The expert panel consistently found a number of health effects in reports, reviews and research. But they concluded that, even for those with the highest exposure levels, health effects were still "within normal ranges" for the whole population.

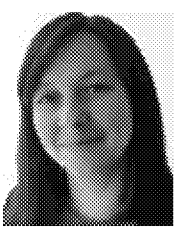
Fears not allayed, says MP

Meryl Swanson, member of parliament for Paterson, New South Wales, an area affected by contamination from PFASs, told Chemical Watch the report "in no way answered questions or allayed fears".

Ms Swanson called the report "contradictory" and cited the summary, which advises both that "important health effects for individuals exposed to PFASs cannot be ruled out based on the current evidence"; and that "evidence does not support any specific biochemical or disease screening or other health interventions for highly exposed groups in Australia, except for research purposes".

She also expressed anger at the timing of the 400-page report's release. It was dated March, but published on 7 May on the eve of the Federal budget, a particularly busy time for parliament, she said.

More available on CW+AsiaHub.



Ellen Tatham

Asia reporter

Related Articles

- PFHxS added to REACH candidate list
- Australia's defence department regrets three-year delay in PFAS warning
- Australian panel: PFASs ill-health links limited or non-existent

Further Information:

- PFAS Expert Health Panel report to Minister
- PFAS Expert Health Panel summary of report
- Department of health – PFAS health effects and exposure pathways

American Chemistry Council defends EPA 'secret science' proposal

Trade body backs non-linear models, increased transparency

10 May 2018 / Data, Exposure modelling, United States

The American Chemistry Council has defended aspects of the US EPA's new science transparency proposal that have come under fire from NGOs.

Formally issued late last month, the agency's proposed rule on "secret science" seeks to allow increased transparency and public validation of studies underpinning agency regulatory decisions.

Among other provisions, it proposes to "increase transparency of the assumptions underlying dose response models". NGOs have raised the alarm that discarding default linear dose models will remove health-protective assumptions and "invite literally an infinite number of model options" on which the agency can base its decision.

But the ACC argues that the EPA has this aspect of the policy right. "For far too long and far too often EPA has relied on default linear dose-response models that have frequently resulted in inflated risk estimates," the trade group said in a blog post.

These, it says, create "misperceptions and confusion about true risks and can lead to unwarranted and costly risk management decisions."

Default linear models concerns

The ACC told Chemical Watch that an example of this occurred with the draft Integrated Risk Information System (IRIS) risk assessment of formaldehyde. It says the programme's use of "overly conservative default assumptions" led it to

proposing a cancer risk value at 0.008 parts per billion – a level significantly lower than the 0.8 to 8.0ppb reported to naturally occur in humans.

The IRIS formaldehyde assessment prompted a scathing review from the National Academy of Sciences (NAS) in 2011. And industry has continued to question the science underlying the programme's conclusion.

The ACC also pointed to the case of 1,4-dioxane, in which the EPA's use of a default linear approach served as the basis for a drinking water guidance as low as 0.35ppb. The trade group said that Health Canada, the EU and other authoritative bodies have concluded the substance acts by a non-linear mechanism, resulting in a drinking water guidance of 350ppb.

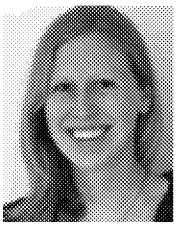
The EPA's plan to consider non-linear models is not satisfying an industry 'ask', added the ACC. Instead, it is "simply a recognition by EPA that old default assumption may not always represent the most up to date science".

Transparency

Separately, the ACC's formaldehyde panel has taken aim at critics who have suggested that industry groups would attempt to use the EPA's new policy to discredit legitimate studies underpinning health protections.

"Industry does not seek access to research to discredit it nor to limit regulation," said the formaldehyde group's blog post.

"In order to help improve public confidence in the decision-making process, it is critical data be made available in a timely and transparent way to ensure decisions are based on scientifically defensible information," the post said.



Kelly Franklin

North America editor

Related Articles

- US EPA proposes controversial science transparency rule
- US EPA science policy to 'change agency culture' on data
- Opening up IRIS
- ACC calls for inclusion of industry analysis in formaldehyde assessment
- TSCA could be undercut by 'secret science' requirements

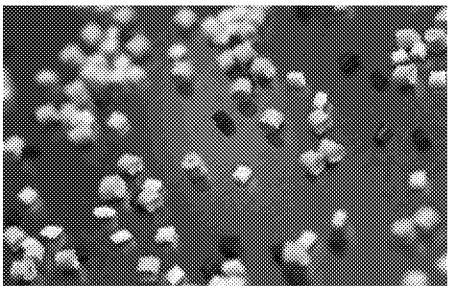
Further Information:

- ACC blog
- Formaldehyde panel blog

EU seeks proposals for 'polymers of concern' project

Contractor will propose criteria for use under REACH

10 May 2018 / Europe, REACH, Risk assessment, Substance registration, Substances of concern



The European Commission is seeking proposals for a project on how "polymers of concern" (PoCs) could be identified and registered under REACH, according to a call for tenders, which has opened.

REACH does not currently require registration or evaluation of polymers, but under Article 138(2) the Commission is required to review the risks they pose and the need for registration of certain types of polymer.

A 2015 study conducted for the Commission proposed two possible registration systems. The first system was based on identification of polymers of low concern (PLCs) and lower or no registration obligations for them; the second on grouping similar polymers.

According to the current call, the successful contractor will:

- propose criteria for the identification of PoCs, including the possibility of grouping based on physico-chemical properties or indication of hazard;
- estimate the potential risks to human health and the environment posed by them, compared with other substances; and
- provide a detailed cost-benefit analysis of the registration requirements for the purposes of impact assessment.

One of the primary tasks will be to "assess which registration requirements would be appropriate for PoCs under REACH". The call for tenders does not discuss registration of polymers that do not meet the PoC requirements.

The maximum budget for the project is €300,000.

Mirror image

Speaking at this week's Chemical Watch Food Contact Regulations Europe 2018 summit, Paul Ashford, managing director of Anthesis-Caleb, said the new project would be a mirror image of the 2015 study that proposed the PLC system. But it was time to ask the authorities to address the polymer identity question, Mr Ashford said.

"If you start to deal with polymers of concern, you have to decide pretty quickly what your polymer substance is," he told the audience in Brussels. "The interesting thing about the Commission's request for a proposal is that is has no mention whatsoever of any further interrogation about what a polymer substance is.

"So this is really speeding up the supply chain bit, saying [stakeholders in the supply chain] really need to engage at least with the [successful contractor], and probably with Echa as well, on this agenda to make sure there is no misunderstanding of at least where the industry has got to on this subject.

"I think the plea the supply chain would make, is it wants to do this with as many downstream user industries as possible, and understand that we are not crossing each other's purposes."

Related Articles

- Study analyses options for REACH polymers registration

Further Information:

- Invitation to tender
- Technical specifications

CIA urges UK government accord on Echa associate membership

High level meetings must transcend a 'temperature check'

10 May 2018 / Europe, United Kingdom

The UK Chemical Industries Association is calling for swift progress towards a "joined-up" approach between itself and the British government on a post-Brexit associate membership of Echa.

Such an approach would pave the way to advancing proposal talks at EU level, CIA head Steve Elliott has told Chemical Watch.

Ahead of a second high level meeting with UK government departments later this month, Mr Elliott said it is essential that the chemicals industry's view of associate membership "chimes" with that of Whitehall.

There is no point, he added, in the UK sector approaching European chemicals trade body, Cefic, and "trying to join the dots when we're not in line with our own government".

At the Chemical Watch Brexit conference on 17 April, Mr Elliott outlined the terms to be considered by both sides of the negotiations as part of an associate membership agreement. They are:

- recognition under EU law and acceptance by both parties of registrations, authorisations, approvals and notifications obtained by UK and EU27 companies;
- existing compliance activities to remain valid and the establishment of a process to avoid reapplications in the EU and UK;

- a mechanism to allow the UK to negotiate access to the Echa database to ensure ongoing and future compliance efforts;
- authorities carrying out assessments on products undergoing testing, registration or authorisation processes at the point of exit, to be allowed to complete them; and
- the UK to continue participating in and maintaining responsibilities under Echa's regulatory processes.

In March, the CIA and Cefic issued a joint statement, in which they called for continued UK participation in Echa. Next, if UK industry – with governmental approval – can get into a position where it is "joined up on some of the detail" with Cefic, Mr Elliott said the proposal has a better chance of support across the Channel.

'Helpful' meetings

In March, the CIA and other industry representatives took part in an inaugural meeting with various government departments to discuss Brexit topics. Subjects included associate membership and rules of origin and the impact they would have on customs arrangements.

Officials from the environment ministry (Defra), the business department (Beis) and the Department for Exiting the European Union (DExEU) attended.

The meetings, which take place every six to eight weeks, are "helpful" Mr Elliott said because it is not just one government department talking to industry. "It's also helpful that an industry like ours, which quite often has been away from the spotlight, now has quite a high profile."

The challenge, he added, is that the UK has to agree a headline deal on Brexit terms with the EU27 by October, "and if that means we've got to work up quite a level of detail then we haven't got long".

What "can't happen", he said, is for the group to do "a temperature check" each time it meets. It needs to have worked out specifics of "what's really important for our industry and our customers, so the officials who are negotiating understand what's valuable and what they could give away more cheaply in negotiations".

And what industry does not want, he said, is time wasted on negotiations from Brexit day of March next year until December 2020 – the date the tentative transition period ends, if formally agreed in the first instance.

That period, he said, "is supposed to be about preparing. The more the UK can do up front the better, to give us that period of grace to get business sorted, rather than ongoing negotiation and a lack of clarity until December 2020 and then suddenly things change overnight."

During a debate on the EU Withdrawal Bill on 8 May, Parliament's House of Lords voted through an amendment that would allow the UK to continue to participate in, or have a formal relationship with, the EU agencies after exit day.

Luke Buxton

Europe desk editor

Related Articles

- Prime minister: UK to seek 'associate membership' of Echa
- UK chemicals industry sees progress, but Brexit 'clock ticking furiously'
- Chemicals industry welcomes Brexit transition period agreement
- UK's ability to keep pace with REACH changes threatened by Bill amendment

Further Information:

- CIA, Cefic joint statement
- Transcript of House of Lords debate
- EU Withdrawal Bill (amended as of 9 May)

UK government denies ban on wet wipes

10 May 2018 / Alternatives assessment & substitution, Microplastics, United Kingdom

The UK says it is not planning a ban on wet wipes, as was recently widely reported in the media, but is working with industry to find "suitable alternatives" that consumers can safely dispose.

Wet wipes, also known as wet towels or baby wipes, are small, moistened pieces of paper or cloth used for cleaning purposes. They contain plastics which, when flushed down the toilet, can block sewers and slowly break down into microplastics that in turn cause harm to marine life.

Reports across the UK media this week suggested that wet wipes would be banned as part of the government's 25-year environment plan, which aims to eliminate all avoidable plastic waste by the end of 2042.

The Department for Environment, Food & Rural Affairs (Defra) subsequently clarified the position, saying that while eliminating single-use plastic waste is one of the government's top priorities, "we have not announced plans to ban wet wipes".

Defra said it is working with manufacturers and water companies to understand which types of wet wipes cause sewer blockages, and make sure labelling on the products "is clear and people know how to dispose of them properly".

Authorities are employing tougher controls on microplastics pollution. The UK ban on the manufacture of cosmetics and personal care products containing plastic microbeads came into effect in January. A ban on sales of such products will follow on 30 June.

Related Articles

- UK promises post-Brexit chemicals strategy that reflects future relations with EU
- UK microbeads ban enters into force

Further Information:

- Defra blog

US EPA round-up

10 May 2018 / United States

IRIS ammonia agenda

The EPA's Integrated Risk Information System (IRIS) programme has released a preliminary agenda for its public science meeting on ammonia.

The 23 May web-based meeting will cover the IRIS Assessment Plan (IAP) non-cancer assessment for oral exposure to ammonia and ammonium salts. The programme is accepting public comments on this through 16 May.

ELAB members sought

The agency is accepting nominations to its Environmental Laboratory Advisory Board (ELAB). This is an advisory committee tasked with providing advice and recommendations to the EPA's leadership about "issues related to enhancing EPA's measurement programmes, and facilitating the operation and expansion of national environmental accreditation".

Related Articles

- US ammonia ingestion study to focus on drinking water concerns

Further Information:

- Public meeting
- ELAB notice

EU consultation on 'what worked well' with 7EAP

10 May 2018 / Europe

The European Commission has launched a public consultation to evaluate its 7th Environmental Action Programme – an overarching set of goals guiding the trade bloc's environment policy until 2020.

Launched in 2014, 7EAP has set out a vision for progress by 2050. This has three key objectives:

- to safeguard EU citizens from environment-related pressures and risks to health and wellbeing;
- to protect, conserve and enhance natural capital in the bloc; and
- a resource-efficient, green and competitive low-carbon economy.

The 7EAP also calls on the Commission develop, this year, a strategy for a non-toxic environment that promotes innovation and the development of sustainable substitutes, including non-chemical solutions. In October, the Commission published seven sub-studies that will form the basis of the strategy.

The consultation period will run between 3 May and 26 July, and assess "what worked well, and how it could have been better", the EU executive said.

It will focus on the "structure and strategic role" played by 7EAP and also assess the programme in terms of its "effectiveness, efficiency, relevance, coherence and added value".

All citizens and organisations are invited to comment. The evaluation will also build on contributions from the European Environment Agency (EEA), the EU Environment Implementation Review (EIR) – a tool to improve implementation of EU environmental law and policy – and consultations with member states and specific interest groups.

Related Articles

- EU publishes sub-studies for non-toxic strategy

Further Information:

- Public consultation
- 7EAP

Post-Brexit IT failure a 'substantial risk' to UK chemicals industry

MPs say poor Defra track record could lead to disruption

10 May 2018 / Substance registration, United Kingdom

MPs have said there are "substantial risks", including disruption to the UK's chemicals industry, if the Department for Food, Environment and Rural Affairs (Defra) is unable to properly update its IT systems before the UK leaves the EU.

In March, junior environment minister Thérèse Coffey said Defra had started work on new IT capability to enable the registration and regulation of chemical substances placed on the national market.

But in a recently published public accounts committee report, MPs express doubt at "how realistic" Defra's – as well as the Department for International Trade's – plans are.

"In light of Defra's poor track record in implementing new IT systems in the past," the report says, "we have concerns over the potential for disruption to the agri-food and chemical industries if these IT systems are not ready in time and contingency plans have to be enacted".

Defra says it has has made "good progress" in developing the system, and, the report adds, is optimistic that it can deliver what's required by March 2019, "whatever the outcome of the negotiations".

Speaking at the Chemical Watch conference on 17 April, Defra's James Dancy said the department aims to make the IT system "very much the same" as Echa's, including Iuclid dossiers. He said that the government will start testing the system with industry, although no date for this has been set.

The report says the department's contingency plan, if the system is not ready in time, includes "manual workarounds". Defra said it will "fall back on to manual systems as it seeks to deliver all that it needs to for Brexit, but this could impede or at least slow down imports and exports causing severe delays at the border".

According to the report, the department has "an impossible challenge" and does not have a "clear plan" of top priorities. It must be clear, it says, about what it will "not be delivering as a result of Brexit".

At the time the report was prepared, 20 of Defra's 43 'workstreams' had an IT component. Four of them have a 'build' element in the event of a 'no deal' scenario, the report says. This includes an import control system to facilitate trade in animals and animal products. The department now has 64 workstreams.

Defra must ensure it has the "necessary resources" in place to complete its IT programmes on time and avoid "costly and embarrassing contingencies involving manual completion and submission of forms". The MP told Defra to provide a progress update by the end of June.

Department difficulties

If the Brexit transition period from exit day of 29 March 2019 to December 2020 is formally agreed, it will give Defra more time to develop these systems. But, the report warns, the department "needs to make sure that it doesn't let progress on their development slip, in case negotiations break down".

Its preparations, however, have been "hampered by the pervasive uncertainty" about the UK's future relationship with the EU. This, the report says, leaves not only departments but also businesses "in the dark" about exactly what they need to do to prepare.

In particular, the report notes, Defra has to work up options for the three different scenarios – deal, no deal or transition. This is "time-consuming and costly", it adds.

Related Articles

- UK starts work on post-Brexit chemicals registration system
- UK chemicals industry sees progress, but Brexit 'clock ticking furiously'

Further Information:

- Report

EU to assess existing policies for circular economy plan

10 May 2018 / Alternatives assessment & substitution, Europe, Substances of concern

The European Commission is planning to evaluate existing EU policies to see how they contribute to the circular economy and to identify ways to better meet the initiative's goals.

It has produced a roadmap document which will look at "the soundness and completeness" of existing EU policy and regulatory instruments. The EU executive will then develop preliminary options for further action based on evidence submitted to a public consultation. This closes on 4 June.

It will also include work undertaken in the follow-up to the refit of the EU Ecolabel, a voluntary ecolabelling scheme.

Some of the existing policy tools target specific product groups through market restrictions for the poorest performing products, the Commission said, while others restrict use of certain substances in product groups or generally – with REACH as an example.

Where multiple policy tools address the same products or product groups, the Commission will explore ways of optimising the interactions between them. It aims to generate a policy drive towards more 'circular' products, "while respecting the specificities of the different policy instruments".

Several product groups, it says, are currently not covered by EU policies even though they have a high circular economy potential, such as food and drinks, textiles, construction products/buildings, furniture and cosmetics.

In January this year, the Commission published a series of planned actions and proposed options to combat the problem of substances of concern in products and waste. The plans are included in a Communication on options to address the links between chemical, product and waste legislation and form part of the circular economy action plan.

Related Articles

- EU sets out actions to tackle hazardous substances in waste, products

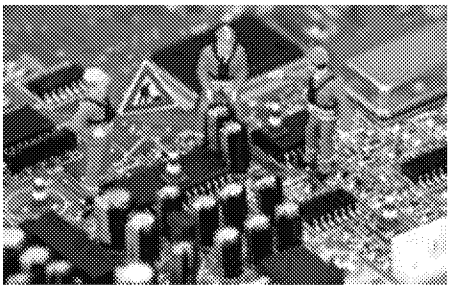
Further Information:

- Roadmap and consultation page

Report finds Samsung workplace link to ill-health unproven

Company not completely exonerated

10 May 2018 / Confidentiality & right-to-know, Electrical & electronics, Legal cases, Occupational hygiene, OSHA, South Korea



There is no clear evidence linking illness with workplace conditions, including exposure to harmful chemicals, at Samsung Electronics, a South Korean independent committee has reported, after completing a two-year investigation.

The committee, established in June 2016 in agreement with workers suffering from a number of illnesses and their families, investigated production lines at the company across South Korea. This included analysing 54 materials used at the company.

Workers and their families have been campaigning for a decade for compensation for diseases – including leukaemia and brain tumours – they say were caused by working at the company.

Stressing that their findings do not necessarily completely exonerate the company, the committee said it could find no link between working at the company and worker illness.

The investigation team, which reported on 24 April, said emissions of potentially dangerous substances were within legal limits; radiation exposure was no different from the general population; and although some toxic substances were found, such as toluene, these were in quantities that posed no effect to health.

Release of company environment reports blocked

The committee's report came just five days after a district court decision to suspend publication of historical workplace environmental reports from Samsung Electronics, ordered by the Ministry of Labour.

The ministry ruled in February that the reports from 2009-2017, not normally made public, should be released to meet concerns about workplace-illnesses raised in the media. However, Samsung immediately filed a motion to overturn the decision.

In South Korea, companies are obliged to conduct "work environment monitoring" by taking and analysing samples from the workplace for harmful substances under the country's Occupational Safety and Health Act (Osha). The reports for Samsung Electronics are said to contain information on workplace exposure to 190 hazardous chemical substances.

The court's decision to suspend publication was prompted by a 17 April report from a panel of semiconductor experts, convened by the Ministry of Trade, Industry and Energy (Motie). The historical reports, said the panel, contained

information on "key national technologies" because they made it possible to guess chip manufacturing technologies and processes.

International campaign

A number of international NGOs and labour groups have criticised Samsung for workplace conditions in South Korea and Vietnam and for blocking disclosure of information on workplace chemical use. Most recently on 1 May, several organisations held a "Global Day of Action Against Samsung" with petitions made to "clean up" the company.

Sunny Lee

Asia editor

Further Information:

- Report of Investigation Committee
- Protests Press Release

TSCA CBI guidance documents a 'missed opportunity'

NGOs seek changes to ease access to protected information

10 May 2018 / Confidentiality & right-to-know, TSCA, United States

A coalition of NGOs says that the US EPA's draft guidance on disclosing confidential information under the new TSCA falls short of what is needed to meet real-world needs.

The comments came in response to the agency's consultation on three guidance documents that outline how certain people can access TSCA confidential business information (CBI) in emergency and specific non-emergency situations.

The EPA issued these consistent with the 2016 amendments to TSCA, which expanded the disclosure of protected information where such data could assist public officials and health professionals helping those at risk from chemical exposures.

But a coalition of 17 NGOs, spearheaded by Safer Chemicals, Healthy Families, says the documents represent a "missed opportunity".

"While dutifully paraphrasing the requirements of the law, they fail to address the larger TSCA goal of enabling front-line professionals and public officials to successfully use the new provisions to meet real-life health and environmental needs," it says.

Changes sought

Among the NGO coalition's concerns is that the intended beneficiaries of the programme, such as first responder and physicians, are unlikely to be familiar with TSCA and legal intricacies around protecting CBI.

As such, the groups recommended the EPA develop outreach and education. And they believe the agency needs to train its staff to ensure "the statutory goal of providing necessary information to officials on the ground will [not] be stymied by poor communication, delays, and bureaucratic snags."

Other NGO commenters and New York's environmental department echoed the coalition in recommending that the EPA include deadlines for how quickly it will process a request, to "avoid unreasonable delays in disclosing information".

And many also asked that the agency develop an electronic system for submitting requests and tracking their status.

More broadly, NGO the Environmental Defense Fund's comments called on the agency to modify the documents to provide an "accurate description" of the confidentiality requirements outlined in section 14 of TSCA.

"EPA needs to accept that Congress consciously chose to impose more stringent substantive and procedural standards on confidentiality claims under TSCA, and that Congress called for wider disclosure of confidential information in this context," it said.

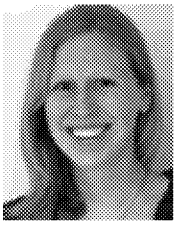
Industry response

Industry groups largely supported the guidance documents, including provisions outlining the obligations on those requesting CBI to maintain the confidentiality of those data.

But the American Chemistry Council expressed concern the agency is not well equipped to respond quickly in emergency situations. It offered the use of its existing Chemtrec emergency response programme to facilitate implementation of this provision.

And the industry group also baulked at a statement in the guidance that suggests the EPA is generally required to release health and safety data. "While ACC agrees that the health and safety effects and results from a health and safety study must be disclosed, the underlying data is not, in fact, 'required' to be disclosed, as the guide suggests," it said.

The EDF, however, squarely disagreed that health and safety data are eligible for protection from disclosure. And it encouraged the agency to clamp down on companies "inaccurately" making overly-broad CBI claims.



Kelly Franklin

North America editor

Related Articles

- US EPA releases guidance for CBI sharing under TSCA

Further Information:

- Docket

Danish investigation finds fluorinated substances in cake packaging

But intentional use has decreased

10 May 2018 / Denmark, Food & drink, Food contact, Halocarbons

Tests carried out in Denmark have found fluorinated substances in paper wrappings used in ready-made cakes.

The discovery comes after a national recommendation to avoid intentionally adding them to food contact materials three years ago.

In three out of 21 baking paper and other cake packaging materials examined, fluorinated substances were detected at such high levels it is "very likely" the substances were intentionally added, the Danish Consumer Council's 'Think Chemicals' initiative said.

There is no specific EU regulation to control harmful chemical substances in paper and board food packaging. But in 2015, the Danish Veterinary and Food Administration introduced a recommendation for manufacturers not to add the substances intentionally to food packaging materials. It is, however, not legally binding.

Think Chemicals said while its tests did not measure the substances inside the cakes, other studies have shown they can migrate to the food and contribute to people's total exposure - the so-called cocktail effect.

A test in 2016 on cake wrappings had revealed intentional use of fluorinated substances. Think Chemicals said this year's retest of the same wrappings indicated their use "has generally decreased".

Investigators found that four samples which contained the substances in 2016 no longer had them.

Last year, Danish tests using a new approach to detect harmful chemicals in FCMs made from paper and board found two phthalates and bisphenol A (BPA) in pizza boxes.

Related Articles

- Danish test finds phthalates and BPA in pizza boxes

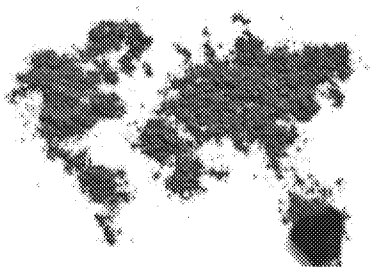
Further Information:

- Press release

CosmeticsEurope: support regulatory compatibility, not harmonisation

Trade group says this will 'maximise compliance' worldwide

10 May 2018 / Cosmetic products Regulation, Europe, Personal care



The global cosmetics industry should not push for global harmonisation of cosmetics regulations, but instead call for compatibility, says Gerald Renner, director of technical regulatory affairs at trade group, CosmeticsEurope.

Speaking at last month's In-Cosmetics regulatory conference in Amsterdam, he said industry interest should not be in "similarly worded laws" across countries and regions.

Instead, it should push for compliance measures, such as product information and notification requirements, that are "portable" between different regulatory approaches.

"All regulations have their historical and cultural backgrounds, and it is hard to overcome that. One size does not fit all," he said.

Harmonised wording, he said, does not mean you will have the same regulatory requirements. For example, he added, many countries have the same definition of cosmetics, but how this is applied is and can be "totally different".

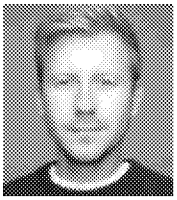
"We want the information and the efforts we take to support regulatory compliance in one country to be used in another," said Dr Renner.

"Whether a law calls it pre-market registration or in-market control, if we can use the same information, and it grants us quick market access, the wording really doesn't matter."

CosmeticsEurope, said Dr Renner, is working on the compatibility of regulatory 'modules' for product information and notification, as well as other requirements.

"However, these laws are implemented around the world, there should be a best practice. Whether we're talking about the Chinese, EU or Israeli approach, we should all have the same understanding of what is needed," he said.

Dr Renner's presentation provided an overview of how different countries regulate cosmetics. He compared rules in China, Taiwan, Australia, the US and India with the EU's cosmetic products Regulation. It showed that some, including China and Australia, are aligning certain measures, such as definitions and animal testing, to the EU's approach.



Leigh Stringer

Global Business Editor

Echa round-up

10 May 2018 / Classification, Europe, Labelling, Microplastics, REACH

Advice on changes to joint submissions

Echa has created a webpage to help registrants identify situations in which they need to contact the agency to request changes to a joint submission once it has been created in REACH-IT. Lead registrants can make some changes themselves but some have to be made by the agency.

The webpage lists six scenarios, including lead role verification, in which such a request would need to be made.

Calls for evidence: restrictions of microplastics and oxo-degradable plastics

It is the last opportunity to provide comments to the agency's call for evidence on the use of intentionally added microplastic particles in products. The deadline is 11 May.

Meanwhile, the deadline for feedback on oxo-degradable plastics has been extended to 31 May.

Webinar: last-minute advice on REACH 2018

A reminder that Echa is running a webinar on 17 May, offering last minute advice on REACH registration with the deadline fast approaching. The event offers the opportunity to pose questions to an expert panel on all aspects of registration.

Workshop on EUSES update needs

The agency is running a workshop looking at what is needed to update Euses, the EU system for the evaluation of substances. This is a decision-support software that enables government authorities, research institutes and chemical companies to carry out a rapid assessment of the risks posed by chemicals.

The main objective is to review the state of the art in environmental exposure assessment, and discussions will be based on recent scientific developments on release estimation and fate assessment within regulatory exposure assessments, the agency says.

The workshop will provide a platform for regulators, industry, academia and other stakeholders of REACH and biocides Regulations to participate in the review.

It is planned from 4-5 June in Brussels.

Update to Echa-term database

The agency has added 45 new terms and their definitions to the Echa-term resource. This is a multilingual terminology database in 23 EU languages, where terms and their definitions can be found and downloaded free of charge.

The new terms come from:

- the *Practical guide for SME managers and REACH coordinators*;
- Iuclid material; and
- the best practices document on how to prepare registration dossiers that cover nanoforms.

Substance evaluation work translations available

- **Guide on substance evaluation**: the practical guide How to act in substance evaluation is now available in 23 languages. This describes how authorities evaluate substances and explains registrants' obligations. The guide also addresses data sharing and communication between registrants of the same substance.
- **Summary of 2017 evaluation report**: The summary and recommendations of the agency's annual progress report on evaluation under REACH are now available in 23 languages. The recommendations help new and existing registrants to comply with REACH requirements and improve the quality of their dossier.

PEG consultation on revised CLP guidance

Echa has sent draft *Guidance on labelling and packaging under CLP* (version 4.0) for Partner Expert Group (PEG) consultation. The guidance has been fully revised. The main changes are:

- alignment with a new annex to the CLP Regulation on harmonised information relating to emergency health response; and
- addition of a new section 6.2, describing the labelling of multi-component products with label examples.

REACH-IT closed 4-5 June

Echa has advised that its REACH-IT tool will be closed from Monday 4 June 00:00 (EEST, GMT+3) until Tuesday 5 June 10:00 (EEST,GMT+3) for maintenance. The tool is not accessible during this period.

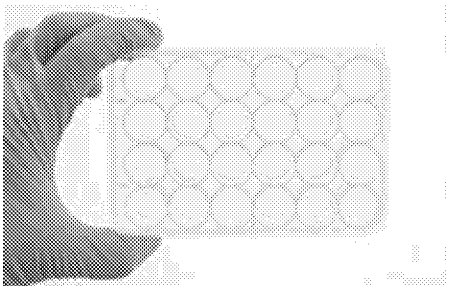
Further Information:

- Joint submissions advice
- Current calls for evidence
- Registration: REACH 2018 webinar
- EUSES workshop
- ECHA-term
- Practical guides
- PEG consultation - draft CLP guidance (version 4.0)

Anses calls for new in vitro genotoxicity tests for titanium dioxide

Inconsistent results have prevented genotoxicity conclusion

10 May 2018 / Classification, France, Nanomaterials, REACH, Test methods



There is an urgent need for new and improved *in vitro* genotoxicity tests for titanium dioxide nanoparticles (NPs), according to the French Agency for Food, Environment and Occupational Health and Safety (Anses).

While collecting carcinogenicity information for hazard assessment of titanium dioxide, Anses found that few *in vivo* studies were good enough to reach a conclusion on genotoxicity. "The low quality of the *in vivo* dataset is likely to lead to possible false interpretation of the genotoxic profile of titanium dioxide NPs," according to a report written by a team from the agency's chemical assessment unit.

"Even if *in vivo* data are considered of higher relevance than *in vitro* data, unfortunately they are too limited to conclude on genotoxicity of titanium dioxide NPs," it writes in *Nanotoxicology*.

Numerous *in vitro* studies are available, but these also give an inconsistent genotoxicity profile, it adds.

Titanium dioxide was added to the Community Rolling Action Plan (Corap) in 2013, but its evaluation has been dogged by issues regarding the identity – the shape, size and coating - of different types of nanomaterials. The difficulties are exacerbated by the myriad uses of the substance.

France updated its Corap justification document in March 2018, stating that "in the absence of reliable *in vivo* assays, there is an essential need for further *in vitro* and *in vivo* investigations of the genotoxicity potential of titanium dioxide NPs".

Room for improvement

Anses found that most *in vitro* studies are on rutile and anatase forms of titanium dioxide. The latter is a photo-catalyst, meaning light could significantly affect test results through formation of reactive oxygen species.

"It is essential to take the effect of light into account when interpreting the *in vitro* genotoxic results obtained from NPs with photocatalytic properties," writes the Anses team.

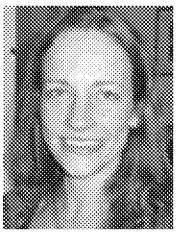
It is also important to choose the cell line carefully and to check that the NPs don't interfere with assay function, it adds. The team calls for *in vitro* tests lasting longer than 24 hours, as well as the standard, shorter assays. This should help to identify a "large range" of DNA damage mechanisms, it suggests.

Negative genotoxic results should be confirmed by checking how the cell line responds to NP exposure and whether the NPs could prevent the test system from working as it should.

Finally, the Anses team calls for studies to be reported in detail, with access to raw data. This is "essential for an adequate explitation by regulatory bodies", it says.

Because TiO_2-NP toxicity is a "topic of interest for society", the agency expects an increase in published data. But it strongly reminds researchers that the "quality needs to be improved over quantity of data".

In 2017, Echa's Risk Assessment Committee decided that TiO_2 should be classified as a category 2 carcinogen by inhalation. Some EU member states suggest that the classification should not be directly translated into CLP but should have a split entry based on particle size or form.



Dr Emma Davies

Reporter

Related Articles

- Poorly soluble, low toxicity particles facing review
- EU member states support change to titanium dioxide classification

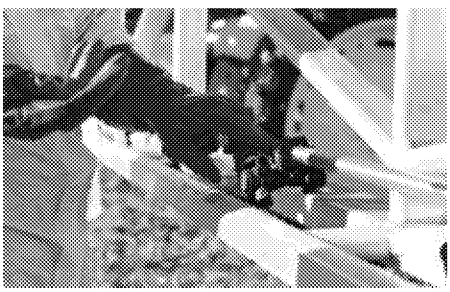
Further Information:

- Nantoxicology article (abstract)
- France's Corap justification

North American organisation examines presence of PFASs in apparel

Study targets 31 substances

10 May 2018 / North America, PFCs, Product testing, Textiles & apparel



A study conducted by the Commission for Environmental Cooperation, a trinational organisation created by Canada, Mexico and the US, has examined 137 articles of clothing and apparel for the presence of PFAS substances.

PFASs (per- and polyfluorinated substances) are used in a wide range of consumer products for their heat, water and oil resistant properties. According to the US EPA, the group of compounds are persistent, resist degradation in the environment and bioaccumulate.

"The degree to which they can migrate out of apparel and contact the skin or saliva of the wearer, or enter the environment, can be a concern," the study says.

It was undertaken because, although environmental monitoring data is available, only limited information exists on the substances' presence and trends in consumer products, including children's items.

The degree to which [PFASs] can migrate out of apparel and contact the skin or saliva of the wearer, or enter the environment, can be a concern, CEC study

Consequently, last summer, the CEC, established under the North American Agreement on Environmental Cooperation (NAAEC), analysed articles of clothing and performance apparel, including children's items, purchased from 27 cities across North America.

Targeting 31 PFAS compounds, it found that 97 articles, or 68.6%, showed positive results for at least one.

Of the articles tested, outdoor jackets presented the highest number of "positive hits". The most frequently detected compounds were perfluorooctanoic acid, or PFOA, (45%) and PFHxA (43%). But low concentrations of PFOS were also found, which the study says may "confirm improvements in the implementation of PFAS regulations in various sectors".

Action on PFAS

In 2009, PFOS was added to Annex B of the UN treaty, the Stockholm Convention on persistent organic pollutants (POPs). This annex requires parties to the convention to take measures to restrict the production and use of the chemicals listed.

Other PFASs have been targets of international and regional regulatory action. PFOA and PFHxS are being considered for listing under the Stockholm Convention.

US state policy experts have predicted addressing PFOA, PFOS and related substances will be the biggest emerging chemical regulation issue at state level this year.

And in December 2017, the US EPA announced a cross-agency effort to address PFASs. However, the agency has not promised regulatory action.

In Europe, the Swedish Chemicals Agency, Kemi, and Germany's federal environment agency (UBA) have submitted a joint proposal to Echa to restrict the manufacturing and placing on the market of six PFASs. And in July last year the Nordic Council, an intergovernmental cooperation body representing five countries, called for prompt regulatory action on the substance group.

In 2006, the US EPA invited eight major fluoropolymer and telomer manufacturers to participate in its PFOA stewardship programme, where they made voluntary corporate commitments to eliminate PFOA and related chemicals from emissions and products by 2015.

Manufacturers in Europe, the US and Japan have largely phased out PFOA. However, its use in other countries, particularly China, has meant that it is still finding its way into the environment.

Meanwhile, a report from Australia's expert health panel for PFAS has concluded that evidence linking exposure to PFASs with human disease is limited or non-existent.

The CEC study is part of its *Greening of Chemicals in North America* project, which aims to develop knowledge useful to chemical risk assessment and/or risk management in the three countries.

The CEC's broader mission is to address "regional environmental concerns, help prevent potential trade and environmental conflicts and promote the effective enforcement of environmental law". It says it "complements the environmental provisions of the North American Free Trade Agreement (Nafta)".

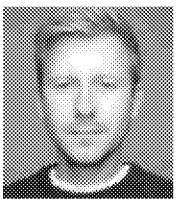
From the PFAS family

perfluorooctanoic acid (PFOA)

perfluorooctanesulfonic acid (PFOS)

Perfluorohexane sulfonic acid (PFHxS)

Perfluorohexanoic acid (PFHxA)



Leigh Stringer

Global Business Editor

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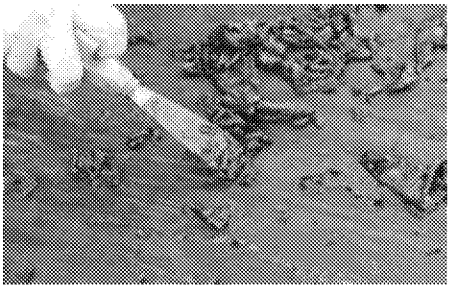
Further Information:

- CEC study

US EPA commits to act on methylene chloride paint strippers

Move follows Pruitt meeting with substance victims' families

10 May 2018 / Built environment, Solvents, United States



The US EPA has announced it will move forward with finalising its proposed rule addressing methylene chloride paint strippers.

Issued in the final days of the Obama administration, the proposal would see a prohibition on consumer and commercial paint stripping uses for methylene chloride. It also proposes to restrict or ban a replacement solvent, N-methylpyrrolidone (NMP).

The agency had suggested in recent months it would be shelving the rule. But in a statement today it said it intends to finalise the proposal. And it is working to send the finalised rulemaking to the White House Office of Management and Budget (OMB) "shortly".

However, while the statement from the EPA refers to "the methylene chloride rulemaking", it is not immediately clear if such a rule would also address NMP.

The agency also confirmed that it does not plan to reevaluate the hazard posed by paint stripping uses of methylene chloride. Instead, it will rely on its previous risk assessment, which identified a range of adverse health effects or death in workers and consumers.

The Halogenated Solvents Industry Alliance (HSIA), representing methylene chloride producers and users, had asked the agency not to adopt the rule. Instead it requested a review of paint stripping under its upcoming TSCA risk evaluation of the substance. Such an approach, it said in 2017 comments to the agency, would allow the EPA to address what the HSIA calls "serious data quality concerns" with the existing risk assessments upon which the proposal is based.

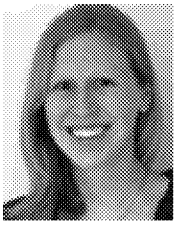
Pressure to act

The EPA's announcement comes just two days after NGO campaigners and families of those who have died using the products met with EPA Administrator Scott Pruitt to urge action on the proposal. It also comes amid an aggressive push on home improvement retailers to pull the products.

Liz Hitchcock, acting director of Safer Chemicals, Healthy Families, praised the work of the families who "have turned their grief into action".

And Sarah Vogel, vice president of health at NGO the Environmental Defense Fund, said she is "encouraged that today EPA has decided to reverse course and move forward to finalise its proposed rule". She also applauded that the agency would not be reevaluating the paint strippers.

But Dr Vogel cautioned that the statement falls short of committing to a ban. "We will delay any celebration until paint strippers containing this deadly chemical are actually off the market," she said.



Kelly Franklin

North America editor

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Further Information:

- Press release

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